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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/649,873

08/28/2003

Amnon Peled

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04/30/2008

EXAMINER

HISSONG, BRUCE D

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/649,873	Applicant(s) PELED ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54, 56-76, 83-84 is/are pending in the application.
- 4a) Of the above claim(s) 1-52, 56-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53, 54, 83 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/5/2008 has been entered.

2. Claims 1-54, 56-76, and 83-84 are currently pending. Claims 1-52 and 56-76 are withdrawn as non-elected subject matter. Claims 53-54 and 83-84 are the subject of this office action.

3. All rejections set forth in the previous office actions are withdrawn in response to Applicants' amendments to the claims. However, Applicants' amendments have necessitated new grounds of rejection under 35 USC 112, first paragraph, as set forth below.

Claim Objections

1. The Examiner suggests amending claims 53 and 83 to amend the phrase "an effective amount of a peptide having the amino acid sequence" to recite "consisting" or "comprising" rather than "having".

2. The Examiner suggests that the syntax of claims 53 and 83 can be improved by replacing the phrase "subjecting the chemokine to an effective amount" with "contacting the chemokine with an effective amount".

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Rejection withdrawn

Rejection of claims 53-54 and 83-84 under 35 USC § 112, first paragraph, regarding lack of enablement for methods of treating disease by administering the claimed peptides, as set forth on pages 2-4 of the office action mailed on 8/6/2007 and the advisory action mailed on 1/14/2008, is withdrawn in response to Applicants' amendments to the claims to delete the limitations of disease treatment. Furthermore, due to Applicants' amendments to recite peptides identified by specific SEQ ID NO, the rejection as it pertained to the excessive breadth and unpredictability of peptides comprising additional amino acids up to 20 residues in length is also withdrawn.

Rejection necessitated by amendment

Claims 53-54 and 83-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the binding of a chemokine to a chemokine receptor, wherein the biological activity of said chemokine is inhibited, does not reasonably provide enablement for a method resulting in all other types of modulation of chemokine binding, resulting in inhibition of all possible activities of said chemokine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims of the instant invention are drawn to a method of modulating the binding of a chemokine to a chemokine receptor, wherein said method comprises subjecting said chemokine to an effective amount of a peptide having the amino acid sequence of SEQ ID NOs 76 or 64. Given the broadest reasonable interpretation, the term "modulating" can encompass inhibition of binding, increasing binding, or changes of the length of time or strength of chemokine-chemokine receptor interaction. The specification provides guidance and examples showing that the claimed peptides inhibit the binding of specific chemokines to chemokine receptors. However, there is no guidance or examples showing that the claimed peptides are capable of modulating, to any degree, any other facet of chemokine-chemokine receptor interactions. Given the guidance of the specification, a person of ordinary skill in the art would conclude that the claimed peptides are chemokine antagonists/inhibitors, and would therefore not be able to predict how to use the claimed peptides in methods for any other type of modulation. For example, a skilled artisan would not be able to predict how to practice method of increasing chemokine binding to a chemokine receptor by subjecting a chemokine to the claimed peptides. Thus, a person of ordinary skill in the art would require further, undue experimentation in order to practice the claimed methods in a manner which is commensurate with the full scope of the claims.

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Furthermore, the specification provides guidance and examples showing that biological activity of various chemokines is inhibited by the claimed peptides, but does not teach inhibition of any other activity. Given the broadest reasonable interpretation, chemokine "activity" can encompass well-known biological activities/effects mediated by binding of the chemokine to its receptor, or other activities, such as the ability to function as an antigen when exposed to an appropriate host, or the ability to be bound by a specific antibody. Thus, given the broad nature of all possible chemokine activities, and the guidance of the specification showing that biological activity of various chemokines is inhibited by the claimed peptides via their ability to inhibit the binding of a chemokine to a chemokine receptor, one of skill in the art would not be able to predict that other types of chemokine activity would be inhibited. Therefore, further, undue experimentation would also be required in order to practice the claimed methods for inhibiting any chemokine activity other than "biological activity".

Claim Rejections - 35 USC § 112, first paragraph - written description

Rejection of claims 53-54 under 35 USC § 112, first paragraph, regarding lack of written description for the genus of peptides comprising two adjacent histidines, at least two amino acids selected from P, T, L, R, W, and F, and having an overall positive charge, as set forth on pages 5-6 of the office action mailed on 8/6/2007, is withdrawn in response to Applicants' amendments to the claims to identify the claimed peptides by specific SEQ ID NO.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claims 53-54 under 35 USC § 112, second paragraph, as being indefinite regarding undefined acronyms, as set forth on page 7 of the office action mailed on 8/6/2007, is withdrawn in response to Applicants' amendments to the claims to define the recited acronyms.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Rejection of claims 53-54 under 35 USC § 102(b) as being anticipated by Eriksson *et al*, as set forth on pages 7-9 of the office action mailed on 8/6/2007, is withdrawn in response to Applicants' amendments to claim 53 to recite a peptide having the sequence of SEQ ID NO: 76. Eriksson does not disclose a peptide having the sequence of SEQ ID NO: 76; accordingly, the rejection is withdrawn.

2. Rejection of claims 53-54 under 35 USC § 102(e) as being anticipated by Kovesdi *et al*, as set forth on pages 9-11 of the office action mailed on 8/6/2007, is withdrawn in response to Applicants' amendments to claim 53 to recite a peptide having the sequence of SEQ ID NO: 76. Kovesdi does not disclose a peptide having the sequence of SEQ ID NO: 76; accordingly, the rejection is withdrawn.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong

Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647